

REMARKS

The applicant submits the following remarks which address each concern raised by the office in the first substantive communication on the merits mailed August 25, 2004.

Specification Amendment: The applicant respectfully requests entry of the amendment to the priority claim to insert the United States patent number to which priority is in part claimed.

Replacement Sheets: The applicant submits 11 replacement sheets of formal drawings without the addition of new matter to replace informal drawing sheets 1 through 11 originally filed with the application.

Cancellation of Claims: The applicant cancels without prejudice claims 176, 181, and 188. The applicant does not waive any right to have these claims examined in a subsequent continuation, division, continuation-in-part, or other continuing application without reduction in breadth or scope or to submit new claims supported by description which claim aspects of the same invention or different inventions, as the applicant deems appropriate.

Claim Amendments: The applicant respectfully requests entry of the claims amendments, as set forth above.

New Claims: The applicant respectfully requests entry of new claims 201 and 202.

Novelty Concerns Under Section 102(b): A claim is anticipated only if “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of*

California, 814 F.2d 628, 631 (Fed. Cir. 1987); *MPEP* 2131. “The identical invention must be shown in as complete detail as is contained. . .in the claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1225, 1236 (Fed. Cir. 1989).

The Imbert Reference. The office has raised novelty concerns with respect to claim 173 as anticipated by United States Patent No. 5,601,077 to Imbert (the “Imbert Reference”). Claim 173 as amended can be differentiated from the technology disclosed by the Imbert reference by elements d. and e. *Claim 173 as amended.* Elements d. and e. recite a “stream delivery aperture” and the step of “streaming said dose” respectively.

As described by the applicant, “A stream delivery element (6) may be coupled to the aperture, as shown in Figures 2, 3 or 6, to prevent the dose from being delivered as discrete particles but rather delivered as substantially continuous concentrated stream.” *Specification at p. 13, ll. 29-31.* There are advantages of the “stream delivery” method as claimed. For example “with respect to cold-adapted viruses delivered intranasally from devices designed to provide a fine aerosol or heterodisperse aerosol, a portion of the dose may remain suspended in the respired air and subsequently exhaled without deposition. . . . Alternately, the cold-adapted virus having a somewhat larger particle size may remain suspended and then deposited in the lung compartment. Once in the lung compartment the virus may be prohibited from replication by exposure to the normal body temperature of the animal. In either event, a portion of the dose may be rendered ineffective because the dose was delivered as a particle of non-optimal size.” *Specification at p. 4, ll. 21-29.*

The Imbert Reference does not disclose a “stream delivery aperture” or the step of “streaming said dose”. Imbert repeatedly discloses “a spray aperture” or “spray nozzle”. *Imbert Reference at column 5, line 2; column 5, line 6; column 5, line 21.* A device which sprays, or the step of spraying a dose as discrete particles, small drops, or a heterodisperse aerosol is entirely different from the applicant’s claimed invention recited by claim 173 which delivers the dose as a stream *Specification at page 14, lines 7-10.*

Because the Imbert Reference does not disclose a “stream delivery aperture” or the step of “streaming said dose”, claim 173 cannot be anticipated by the Imbert Reference. As such, the applicant believes claim 173 as amended is in condition for allowance and respectfully requests allowance of claim 173 along with dependent claims 174-189.

The Jansen Reference. The office has raised novelty concerns with respect to claims 173 as anticipated by United States Patent No. 6,382,204 to Jansen et al. (the “Jansen Reference”). However, the applicant’s claimed priority date precedes the filing date of the Jansen Reference and the Jansen Reference must be withdrawn. *See applicant’s Preliminary Amendment filed March 27, 2002.*

Obviousness Concerns Under Section 103: To establish a prima facie case of obviousness three criteria must be met. First, the prior art reference or combination of references must teach or suggest all the claim limitations. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCP 1974). In determining if all the claim limitations are taught by a combination of references, “all words in a claim must be considered in judging patentability of the claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1070). Second, there must be some suggestion or motivation to modify the reference or combine the teachings. *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ 2d 1453, 1457-58 (Fed. Cir. 1998). Third, there must be a reasonable expectation of success of the making the invention from the combined reference teachings. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). If an independent claim is nonobvious, then any claim depending therefrom is non-obvious. *In re Fine*, 837 F.2d 1071, 5 USPQ 2d 1596 (Fed. Cir. 1988).

The office has raised obviousness concerns with respect to claims 174-189 as being unpatentable over the Imbert Reference, the Jansen Reference, United States Patent No. 5,702,362 to Herold et al. (the “Herold Reference”), United States Patent No. 5,289,818 to Citterio et al. (the “Citterio Reference”), United States Patent No. 4,767,416 to Wolf et

al. (the “Wolf Reference”), and United States Patent No. 5,026,825 to Grebow et al. (the “Grebow Reference”).

The Imbert Reference. As discussed above, the Imbert Reference does not disclose the step of “streaming said dose”. As such, the Imber Reference alone cannot establish a prima facie case of obviousness.

The Jansen Reference. As discussed above, the Jansen Reference must be withdrawn because the applicant’s claimed priority date precedes the filing date of the Jansen Reference.

The Wolf Reference. The Wolf Reference does not disclose the step of “streaming said” as recited by claim 173. The Wolf Reference discloses a “liquid spray tip”. *Wolf Reference, Column 2, lines 19-21.* See also Figure 1 which shows a “spray” emitted from the “liquid spray tip”. As such, the combination of Wolf Reference with Imbert Reference and the Jansen Reference does not establish a prima facie case of obviousness.

The Citterio Reference. Similarly, the Citterio Reference does not disclose the step of “streaming said dose”. Rather the Citterio Reference discloses that “the medicament emerges in the form of a spray”. *Citerio Reference, Column 3, lines 15-18.* As such, the combination of the Citterio Reference, with the Wolf Reference, the Imbert Reference, and the Jansen Reference does not establish a prima facie case of obviousness.

The Grebow Reference. The Grebow Reference does not disclose the step of “streaming said dose”. Rather, the Grebow Reference teaches administering as a spray, aerosol, or drops. *Grebow Reference, Column 11, lines 10-20.* Moreover, the Grebow Reference teaches away from “streaming” as recited in claim 173 indicating that “nasal spray solutions are especially preferred”. *Grebow Reference, Column 11, line 37.* As such, the combination of the Grewbow Reference, the Citterio Reference, the Wolf

Reference, the Imbert Reference, and the Jansen Reference does not establish a prima facie case of obviousness.

The Herold Reference. The Herold Reference does not disclose the step of “streaming said dose”. Rather the Herold Reference discloses an “applicator [which] includes a storage container which is filled with powdery medicare cut 4 (formulation).” *Herold Reference, Column 3, lines 20-21.* As such, the combination of the Harold Reference, with the Grewbow Reference, the Citterio Reference, the Wolf Reference, the Imbert Reference, and the Jansen Reference cannot establish a prima facie case of obviousness.

Because individually or in combination the references cited by the office do not disclose all the limitations of claim 173, a prima facie case of obviousness cannot be established by the office. In view of the discussion above, claim 173 is believed to be allowable as amended along with claims 173-175, 177-180, 182-187, 189, 201, and 202 as amended which are made ultimately dependent on an allowable base claim.

CONCLUSION

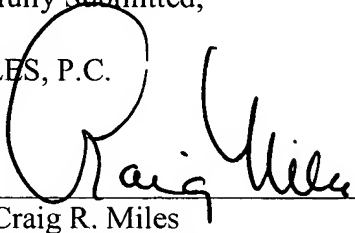
The applicant amends the specification to insert the patent number and issue date of the United States patent to which priority in part is claimed. Claims 176, 181, and 188 have been cancelled without prejudice. Applicant requests entry of new claims 201 and 202. The applicant further requests reconsideration of claims 173-175, 177-180, 182-187, 189, 201, and 202 as amended. The applicant believes claims 173-175, 177-180, 182-187, 189, 201, and 202 as amended are in condition for allowance and respectfully requests allowance at the examiners earliest convenience.

Dated this 23 day of November, 2004.

Respectfully Submitted,

CR MILES, P.C.

By:



Craig R. Miles
ATTORNEY FOR APPLICANTS
USPTO Reg. No. 45,954
1 Old Town Square, Suite 200 B
Fort Collins, CO 80524
(970) 492-0000 telephone
(970) 492-0003 facsimile

DRAWING AMENDMENTS

Replace informal drawing sheets 1 through 11 with the formal drawing sheets 1 through 11 attached to this response.